

**REMARKS**

Claims 1-12 are pending in this application. By this Amendment, claim 1 is amended. Support for the amendment is provided in the specification, for example, on page 3, lines 26-38 and page 4, lines 17-26. No new matter is added. Reconsideration of the application based on the above amendment and the following remarks is respectfully requested.

Entry of the amendment is proper under 37 CFR §1.116 because the amendment: (a) places the application in condition for allowance for the reasons discussed herein; (b) does not raise any new issue requiring further search and/or consideration, as the amendment amplify issues previously discussed throughout prosecution; and (c) places the application in better form for appeal, should an appeal be necessary. The amendment is necessary and was not earlier presented because the amendment is made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

The Office Action rejects claims 1-12 under 35 U.S.C. §103(a) over Bellhouse et al. (U.S. Patent No. 6,328,714) (Bellhouse) in view of Castellano et al. (U.S. Patent No. 5,730,723) (Castellano) and further in view of Schwebel et al. (U.S. Patent No. 3,802,430) (Schwebel). Applicants respectfully traverse the rejection.

The combination of applied references fails to teach, or to have suggested, a needleless injection device comprising a circuit of elements including an initiation device, a pyrotechnic gas-generating charge, and a reservoir containing an active principle, the injection device having a housing, the circuit of elements being in an assembled state, that is accessible from the outside so that a pyrotechnic cartridge can be inserted into the housing directly in the circuit of elements, independently of the other elements, as recited in independent claim 1.

Each of the cited references discloses a device that is structurally different from the injection device recited in claim 1. Bellhouse teaches a reusable device 2 having a

replaceable cartridge 18 comprising a housing 20, a source of compressed gas 22, and a particle container 24 that contains particles of a therapeutic agent. Bellhouse describes the cartridge 18 as "an entirely self-contained, integral component which provides both the particles, and the source of motive force necessary for a single operation of the reusable needleless syringe device" (Bellhouse, col. 6, lines 55-58). As shown in Fig. 7 of Bellhouse, inserting the cartridge 18 into the device includes inserting the source of compressed gas 22 and the particle container 24, which are both part of the cartridge 18. Thus, Bellhouse neither teaches, nor would have suggested, an injection device that includes a pyrotechnic cartridge that can be inserted into the housing directly in the circuit of elements, independently of the other elements.

As shown in Fig. 7 of Bellhouse, the device disclosed in Bellhouse has a cavity 56 into which the gas source 22 is placed. In an assembled state, the cavity 56 is not accessible from the outside, and the gas source 22 can not be inserted into cavity 56 independently of the other elements. Thus, Bellhouse additionally fails to teach or to have suggested an injection device having a housing, the circuit of elements being in an assembled state, that is accessible from the outside so that a pyrotechnic cartridge can be inserted into the housing directly in the circuit of elements.

The other applied references, Castellano and Schwebel, fail to overcome the deficiencies of Bellhouse. The Office Action asserts that Castellano teaches gas powered injectors being equivalent to pyrotechnic charges. The Office Action asserts that Schwebel teaches an encapsulated pyrotechnic propellant charge 25 and a primer activated by a firing pin 27 and a chamber 43 that receives gases produced by the charge 25. Neither Castellano nor Schwebel teach, nor would they have suggested, a needleless injection device comprising a circuit of elements including an initiation device, a pyrotechnic gas-generating charge, and a reservoir containing an active principle, the injection device having a housing, the circuit of

elements being in an assembled state, that is accessible from the outside so that a pyrotechnic cartridge can be inserted into the housing directly in the circuit of elements, independently of the other elements, as recited in independent claim 1.

As described above, the needleless injection device recited in claim 1 differs structurally from each of the devices disclosed in the applied references. The present application describes the desirability of these structural differences, for example, in the fourth full paragraph on page 5, which states

[T]he insertion of the pyrotechnic charge into the device will be able to be done at any stage of the process of assembling the body of the device and in particular toward the end of this process, which will make it possible both to adapt the pyrotechnic charge to the desired depth of penetration and to the nature and/or quantity of active principle present in the device, and also to limit the manipulations of the pyrotechnic charge during the process of assembling the device and thus to reduce the risks of untimely initiation of the charges throughout the assembly process.

The applied references, in contrast, fail to appreciate the desirability of modifying the structure of the disclosed devices to produce a needleless injection device having a pyrotechnic cartridge that can be inserted into the housing directly in the circuit of elements, independently of the other elements.

For at least the foregoing reasons, Bellhouse, even in combination with the applied references, cannot reasonably be considered to teach, or to have suggested, the combination of features positively recited in independent claim 1. Further, claims 2-12 are also neither taught, nor would they have been suggested, by Bellhouse, even in combination with the other applied references, for at least the respective dependence of these claims directly or indirectly on an allowable base claim, as well as for the separately patentable subject matter that each of these claims recite.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-12 under 35 U.S.C. §103(a) as being unpatentable over the asserted combination of applied references, are respectfully requested.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-12 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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